Columbia University Consent Form

Consent Number: (b) (4)
Copied From:
Participation Duration: 2 years
Anticipated Number of Subjects: 730

Contact

Contact	Title	Contact Type	Numbers
(b) (6)	Senior Staff Associate	Study Coordinator	(b) (6)
	Professor	Principal Investigator	
	Asst Prof Of Clinical	Emergency	

Research Purpose

You are invited to participate in a research study to see whether environmental exposures during pregnancy affect the developing infant. This study will provide much needed information on pollution levels in your community, which will be used to develop methods for detecting and preventing health damage from exposure to certain environmental substances.

Information on Research

You were selected as a possible participant in this study because you are a nonsmoking woman residing in Northern Manhattan or the Bronx who attends an OB/GYN clinic of New York Presbyterian Hospital (NYPH) or of Harlem Hospital Center (HHC) and are planning to deliver at NYPH or HHC.

STUDY PROCEDURES

If you agree to participate, we would like your permission to:

· Ask you questions about your pregnancy and your health in general, your home, and to review your's and your baby's medical charts. We will also ask to take a measurement of your head.

· We will also conduct personal, indoor, and outdoor air monitoring at your home by using an air monitor (described below), collecting a dust sample from your home to check for levels of substances that cause allergies, and inspecting your home for leaks, holes in the walls, or any other signs of physical damage that may expose you and your family to rodents, cockroaches, and/or pollutants.

· Around your 30th-31st week of pregnancy, a research worker will come to your home to conduct a short interview, collect a dust sample, and help you in setting up and familiarizing yourself with the air monitor. You will be asked to carry the monitor for 2 days during your 30th-31st week of pregnancy. The monitor is small (41/16 x 315/16 x 2 inches) and light weight (22½ ounces) and is comfortable to wear. It operates quietly and can be placed inside a fashionable backpack, which we will provide. The monitor must be carried by you during the day and placed by your bed while you sleep and during showers. A research worker will return to your home at the end of the 2 days to pick up the monitor.

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· Around your child's first birthday, a research worker will visit your home a second time to collect a dust sample in order to measure the levels of substances in your home that can cause allergies.

· There is also a possibility that your home may be selected by chance, like the flip of a coin, to be more carefully monitored for air pollution and substances that cause allergies. This would mean that a researcher would visit your home 2 additional times. The first visit will occur at 12 months after delivery. At this visit, a research worker would ask you some questions about your home, collect a sample of dust with a small vacuum, and set-up some air monitoring devices in your home. One of these devices is equipped with a collection plate that is the size of a jar cap. The other 2 devices are very similar to the personal air monitor described above. Some simple badges will also be hung both inside and outside of your home to collect air pollutants. In addition, a small instrument will be set up to count particles continuously both inside and outside your home. During this sampling week, we will also measure the air coming in and going out of your home. You will also be asked to complete a daily respiratory symptom diary for 14-days. The researcher workers will call you every two days to remind you to complete the diary. You will be offered an additional $25 for successful completion of the diary. The air pollution equipment will remain in your home for a period of 2 weeks. The second visit will occur at the end of two weeks when the researcher worker will answer your questions if any and will remove all the air pollution monitoring instruments from your home.

· Additionally, we request your permission to obtain a urine sample from you during your pregnancy. We also request that you donate a blood sample (about 2 tablespoons) one to two days after delivery. A sample of left-over blood from the umbilical cord (2-4 tablespoons) will be collected after your infant has been delivered and after the cord has been cut. We will also collect a small sample (approximately 3 teaspoons) of tissue from the placenta, after the doctor has completed his/her examination of the placenta. The placenta is normally discarded after birth and we will collect the sample just before it is discarded. In addition, we will collect a small sample of your baby's first bowel movement (the meconium) from the discarded diaper after your baby has been changed in the nursery. We also ask your permission to draw a small sample of your child's blood (from his/her arm). It will be will be drawn by a pediatric nurse around his/her 2nd birthday (amount equal to 1 teaspoon). None of these procedures will present a risk to your infant. We will check the urine and blood samples to see if there is any indication that your child may be developing allergies or if he/she has been exposed to substances in the environment. We may also check to see if there are genetic or other susceptibility factors that might place you or your child at greater risk from these exposures to substances in the environment. We will take every reasonable precaution to protect the confidentiality of this information, to the extent allowed by law. It is the opinion of the investigators and that of the Columbia-Presbyterian Medical Center Institutional Review Board (the committee that reviews all research studies involving human subjects) that this study is not genetic testing. It is aimed at developing such testing for the future, but cannot currently provide any meaningful information about participants.

· While still at the hospital after delivery, we may ask your permission to include your sleeping infant in a 35-50 minute test to measure breathing, temperature, heart rate and heart rate variability, followed by 6 alternating head-up and head-down tilts to assess physiological responses to blood pressure changes. None of these procedures will present a risk to your infant.

· After birth, you will be contacted every 3 months by phone and asked to answer a few short (b) (4)

questions about the health of your baby. When the baby is 6, 12, and 24 months old, you will be contacted for follow-up assessments to be conducted in the clinic. Infant weight, length, and head circumference will be measured and developmental tests will be given at these visits. The tests will be conducted by researchers trained by (b) (6) a perinatal epidemiologist who specializes in causes of health problems in infants before and after birth.

Risks

Your blood and your 2-year-old infant's blood will be drawn by a needle and the only risk involved may be slight pain or bruising at the place where the blood was taken. There is no risk to your infant during the collection of blood at delivery, as it will be collected from the cord after the cord has already been cut. There is no risk to your infant during the collection of the meconium after delivery, as it will be collected from the diaper after the diaper has been removed from your infant. There is no risk associated with carrying the air monitor. There is no risk to your infant during the tests of physiological response to blood pressure changes. You will not be subject to any experimental procedures.

Benefits

An important benefit provided by the study to you and your child is the careful evaluation of your infant's learning development. Many of these tests are not part of standard pediatric care. If you wish, we will provide the results of all developmental tests to your pediatrician. The knowledge gained from this study will give the community information on air pollution levels in Northern Manhattan and the Bronx. The study may also add to and better explain what is known about the effects of environmental pollution on human health. Thus, the information may be used to set standards on pollution levels.

Additional Costs

There will be no cost to you associated with this study.

Compensation

There will be no cost to you associated with this study. You will be compensated a total amount of $395 for your full participation. If you are also selected for the more in depth home monitoring you will be compensated an extra $25. In addition, your child will receive a toy at the end of the 24 month follow-up visit. Transportation costs to and from required visits will also be provided. Finally, we will be providing your baby with regular developmental testing.

Alternative Procedures

The alternative to participating in this study is not to have the blood and developmental tests and the air monitoring for research purposes.

Confidentiality

Any information you provide during this study that is identified with you will remain strictly

confidential to the extent allowable by law. The law requires reporting of certain information, including evidence of previously unreported child abuse or neglect and evidence that a person is a danger to themselves or others.

Voluntary Participation

Your participation in this study is completely voluntary. You can refuse to participate or withdraw from the study at any time and such a decision will not affect your medical care at New York Presbyterian Hospital now or in the future. Signing this form does not waive any of your legal rights.

Research Related Injuries

(b) (6) or other project investigators have answered your questions to the best of their ability concerning the research and will answer any questions you may have in the future. You are free to withdraw your consent and to discontinue participation in the project at any time.

You have been informed that if you have any questions about this research, you may contact the Principal Investigator, (b) (6) or if you have any questions about your rights as a research subject, you may contact the Office of Institutional Review Board, (b) (6)

CONSENT TO PARTICIPATE IN THE STUDY

I have discussed this study with (b) (6) and/or her associates to my satisfaction. I understand that my participation is voluntary and that I can withdraw from the study at any time without prejudice. I have read the above and agree to enter this research study. Signing this form does not waive any of my legal rights.

I have been informed that if I believe that I have sustained injury as a result of participating in a research study, I may contact the Principal Investigator, (b) (6) or the Institutional Review Board, at (b) (6) so that I can review the matter and identify the medical resources which may be available to me.

I understand that:

a) The New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital;

b) I will be responsible for the cost of such care, either personally or through my medical insurance or other form of coverage;

c) No monetary compensation for wages lost as a result of injury will be paid to me by the Columbia Presbyterian Medical Center, and;

d) I will receive a copy of this consent form.

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Signature

Study Coordinator
Print Name_____Signature_____Date _____

Witness
Print Name_____Signature_____Date _____

Study Participant
Print Name_____Signature_____Date _____

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